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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,021	10/01/2004	Stewart Cole	05394.0022	3824
22852	7590	04/30/2008		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 04/30/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/510,021

**Applicant(s)**

COLE ET AL.

**Examiner**

Rodney P. Swartz, Ph.D.

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4, 5, 7, 9-14 and 18-71 is/are pending in the application.
- 4a) Of the above claim(s) 27, 28, 30-42, 44, 45, 50-56, 58 and 59 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 4, 5, 7, 9-14, 18-23, 29, 43, 46-49, 57 and 60-69 is/are allowed.
- 6) ☒ Claim(s) 24-26, 70 and 71 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☒ Claim(s) 1, 4, 5, 7, 9-14 and 18 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 4 February 2008, is acknowledged. Claims 1, 4, 5, 7, 9, 10, 11, 12, 13, 14, 18, 19, 20, 24, 25, 26, 29, 43, 46, 47, 48, 49, and 57 have been amended. Claims 2, 3, 6, 8, 15, 16, and 17 have been canceled. New claims 60-71 have been added.
2. Claims 1, 4, 5, 7, 9-14, and 18-71 are pending. Claims 27, 28, 30-42, 50-56, 58, and 59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicants request that claims 44 and 45 be withdrawn from consideration.
3. Claims 1, 4, 5, 7, 9-14, 18-26, 29, 43, 46-49, 57, and 60-71 are under consideration.

### **Rejections/Objections Withdrawn/Moot**

4. The rejection of claims 2 and 3 under 35 U.S.C. 112, second paragraph, as being indefinite for "as shown" is moot in light of the cancelation of the claims.
5. The rejection of claims 6, 8, and 15-17 under 35 U.S.C. 112, second paragraph, as being indefinite for "at least genes", is moot in light of the cancelation of the claims.
6. The rejection of claims 2, 3, 6, 8, and 15-17 under 35 U.S.C. 102(b) as being anticipated by Mahairas et al (*J. Bacteriol.*, 178(5):1274-1282, 1996) is moot in light of the cancelation of the claims.
7. The objection to Figures 3A, 3B, and 3C is withdrawn in light of the replacement Figures.
8. The objection to claim 26 is withdrawn in light of the amendment of the claim.
9. The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for "as shown" is withdrawn in light of the amendment of the claim.

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10. The rejection of claims 7 and 9-11 under 35 U.S.C. 112, second paragraph, as being indefinite for "at least genes", is withdrawn in light of the amendment of the claims.
11. The rejection of claims 44 and 45 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from non-elected claims, is moot in light of the withdrawal of the claims by applicants.
12. The rejection of claims 1, 4, 5, 7, 9-11, 44, and 45 under 35 U.S.C. 102(b) as being anticipated by Mahairas et al (*J. Bacteriol.*, 178(5):1274-1282, 1996) is withdrawn in light of the claim amendments and applicants' arguments.

#### Rejections Maintained

13. The rejection of claim 24 under 35 U.S.C. 112, second paragraph, as being indefinite for composition of deposited strains, is maintained.

As newly amended, the claim remains indefinite because the claim recites *M. bovis* BDG **strains**, which have integrated "a" cosmid herein referred to as "either" RD1-2F9 or RD1-AP34, "which are contained in" the *E. coli* strains deposited at the CNCM under the accession number I-2831 and I-2832 respectively.

The claim appears to refer to one cosmid by utilizing the word "a". This single cosmid is referred to by two names. However, the claim also recites "which are" contained in two separate deposited *E. coli* strain. The term "which are" designates two separate cosmids. Clarification is still required concerning how many cosmids are being claimed.

14. The rejection of claim 25 under 35 U.S.C. 112, second paragraph, as being indefinite for "corresponds to", is maintained.

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As newly amended, the claim now recites "said cosmid corresponding to". It remains unclear what are the metes and bounds of such a "correspondence". For example, is the cosmid identical to the SEQ ID NO:3, or some variant.

15. The rejection of claim 26 under 35 U.S.C. 112, second paragraph, as being indefinite for "covers", is maintained.

As newly amended, the claim no longer recites "covers", but "said cosmid corresponding to". The claim remains unclear because now it is indefinite concerning what are the metes and bounds of such a "correspondence". For example, is the cosmid identical to the SEQ ID NO:1, or some variant.

#### **Claim Objections**

16. The listing of claim 2 is objected to because of the following informalities: at the end of claim 2, **"Please ask the inventors to confirm that SEQ ID NO:2 is equivalent to RD1"**. Appropriate correction is required.

#### **Claim Rejections - 35 USC § 112**

17. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

18. Newly added claims 70 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite that "most of the immunogenic peptides" remain intact, but that "functionality is lost".

It is unclear what are the metes and bounds of these two restrictions. First, it is unclear how many peptides constitute "most", and secondly, it is unclear what "functionality" is being designated. For example, is the ability to bind to antibodies lost, or some cellular function.

### **Conclusion**

19. Claims 24, 25, 26, 70, and 71 are rejected. Claim 2 is objected to.
20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. This application contains claims 27, 28, 30-42, 44, 45, 50-56, 58, and 59 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
22. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

April 14, 2008

**Application Number****Application/Control No.**

10/510,021

**Examiner**

Rodney P. Swartz, Ph.D.

**Applicant(s)/Patent under  
Reexamination**

COLE ET AL.

**Art Unit**

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